REMARKS

By way of the foregoing Preliminary Amendment, Applicants have added claims 25-30. The new claims are fully supported by the specification. For example, the specification teaches "any combination" of SEQ ID NOS: 16-21 or fragments thereof, "1-3 copies" of certain elements, or "2 or more monomers". See page 25, lines 5-27, and page 12, lines 15-16, for example. Those skilled in the art would understand that the recitation of "non-naturally occurring manner" is implicitly, if not explicitly, supported by the specification, as Applicants clearly do not intend to claim an isolated nucleic acid comprising the native AOX1 regulatory region. No new matter is introduced by the foregoing amendment.

In the Office Action dated August 22, 2006, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents sixteen separate and distinct inventions.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, claims 1 and 7-20 (as they read on SEQ ID NO: 16), drawn to an isolated polynucleotide comprising a regulatory region containing a nucleotide sequence of SEQ ID NO: 16 or variant thereof. Applicants further respectfully submit that new claims 25-30 all require the presence of SEQ ID NO: 16 in the claimed nucleic acid, and therefore belong to the elected Group I and should be included in the examination.

Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application. However, pursuant to 37 C.F.R. §§ 1.111 and

1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In the first instance, Applicants respectfully submit that the six different nucleic acid molecules, as set forth SEQ ID NOS: 16-21, are all regulatory elements of the Alcohol Oxidase 1 promoter and have been identified under a single inventive concept. Therefore, Applicants respectfully submit that Groups I-VI are different aspects of a single invention. The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of

an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Furthermore, Applicants respectfully submit that Group VII, drawn to an isolated nucleic acid comprising the sequence of SEQ ID NO: 30, should be examined together with Group I. SEQ ID NO: 30 represents a mutant AOX1 regulatory sequence, where the E element (SEQ ID NO: 20) has been deleted from the wild type AOX1 regulatory region. The mutant sequence set forth in SEQ ID NO: 30 is therefore comprised of the combination of SEQ ID NO: 16, 17, 18, 19 and 21. Therefore, SEQ ID NO: 30 is in fact, a nucleic acid comprising SEQ ID NO: 16 and should be examined together with Group I.

Moreover, the Examiner has required restriction between product and process claims. Applicants respectfully submit that process claims 21-22, or at least to the extent these claims read on SEQ ID NO: 16 and SEQ ID NO: 30, should be examined together with Group I. Because the process claims are directed to the use of the product of Group I, they are clearly not "independent and distinct" from Group I. In any event, the Examiner is reminded of the rejoinder practice, where when the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim should be rejoined for examination.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade

and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the

Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined sixteen groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims, or at least claims 1, 7-20, 23 and 25-30, as well as claims 21-22 to the extent that they read on SEQ ID NO: 16 and SEQ ID NO: 30.

Respectfully submitted,

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